

REMARKS

Claims 1-10, 24, 36, 51, 95-104 and 106-118 are pending in this application.

No new matter has been added.

Priority

Applicant thanks the Examiner for the request to recite the priority claim at the beginning of the specification. Applicant has amended the specification accordingly.

Claim Rejection under 35 U.S.C. §102

The Examiner has rejected claim 36 under 35 U.S.C. §102(b) as allegedly being anticipated by Urry (U.S. Patent No. 4,589,882). The Examiner contends that Urry meets the limitation of the claim, namely that the agent is a conjugate of an active agent attached to a linker not native to the active agent.

Applicant respectfully traverses. Urry provides bioelastomers that can be used to repair the natural elastic system in an animal or human body. The bioelastomers can be made up of bioelastomeric polypeptides strengthened with core fibers. These bioelastomers, even when made up of the components recited above, are the “active agent” and not a conjugate of an active agent and linker as provided in the rejected claims. Therefore, Urry does not provide any more than an active agent that can be used to repair the natural elastic system and certainly does not provide the method of the rejected claim.

Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Claim Rejections under 35 U.S.C. §112

The Examiner has rejected claims 36, 106, 107 and 115-117 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner has argued that claims 36 and 117 are unclear because “nativity” is relative to the time that a molecule is observed. The Examiner has also argued that claim 106 fails to further limit claim 36. The Examiner has also argued that claims 115 and 116 fail to further limit claim 114.

Applicant respectfully disagrees. In regard to claims 36 and 117, Applicant maintains that what is considered native or not native would be sufficiently clear to one of ordinary skill in the art based on the teachings provided in the specification, plain language of the terms and the context of the use of the term in the rejected claims. One of ordinary skill in the art would readily recognize that an active agent is any agent that once coupled to a biological tissue *in vivo* or *in vitro*, has, maintains or can be released to have a desired activity, such as a desired biological activity or therapeutic activity. One of ordinary skill in the art would also readily recognize that agents that fall within this definition may or may not have within their structure something that qualifies as a linker as provided by Applicant. If the active agent itself is not a substrate of lysine oxidase, then the active agent would require a linker which is a substrate of lysine oxidase (i.e., a linker not native to the active agent). If the active agent itself is a substrate of lysine oxidase, then the active agent includes a linker which is a substrate of lysine oxidase (i.e., a linker native to the active agent). Therefore, one of ordinary skill would readily recognize that the active agents of claims 36 and 117 are those that do not have within their structure something that is considered a linker as provided by Applicant.

In regard to claims 106, 115 and 116, which according to the Examiner, do not further limit the claims from which they depend, Applicant notes that the specification on page 32, lines 19-21, provides a definition for what is considered a native agent. It is clear from the teachings of the specification as well as the plain language of the term "native active agent" that a native active agent is one as it occurs in nature (isolated or synthesized to duplicate a naturally occurring molecule), without modification or conjugation as described in the specification. The active agent recited in claims 36 and 114 are not limited to native active agents, and the rejected claims do, in fact, further limit claims 36 and 114.

Accordingly, Applicant respectfully requests that the Examiner withdraw this rejection.

Claim Rejection under 35 U.S.C. §103

The Examiner has rejected claims 1-3, 36, 98-101 and 118 under 35 U.S.C. §103(a), as allegedly being unpatentable over Richardson et al. (U.S. Patent No. 5,490,980) in view of Stedronsky (U.S. Patent No. 6,258,872) and Urry (U.S. Patent No. 4,589,882).

Applicant respectfully traverses. In order for an obviousness rejection to be asserted, the Examiner must successfully demonstrate that there would have been a motivation to combine the cited references on the part of one of ordinary skill in the art as well as a reasonable expectation of success in doing so. Applicant contends that the arguments provided by the Examiner do not adequately satisfy these requirements. Accordingly, it is Applicant's belief that this rejection cannot be maintained.

In regard to the motivation to combine the teachings of the references, Applicant notes that the Examiner merely asserts that one of ordinary skill in the art would have been motivated to do so simply because lysine oxidase allegedly serves the same purpose as transglutaminase. This argument, however, falls short from establishing that even if, *arguendo*, lysine oxidase serves the same purpose, then one of ordinary skill in the art would be motivated to use it instead of transglutaminase. In addition, lysine oxidase was known in the art prior to Richardson et al. This is exemplified by Urry. However, even with lysine oxidase being known at the time of Richardson et al., Richardson et al. chose to use transglutaminase, and the teachings presented are specific for this particular enzyme. In fact, Richardson et al. do not even mention lysine oxidase, which the Examiner has alleged is a known equivalent. This is contrary to the Examiner's assertion that one of ordinary skill in the art would have been motivated to use lysine oxidase in place of transglutaminase. There is no evidence that even Richardson et al. themselves considered such a substitution.

In regard to the reasonable expectation of success, the Examiner merely argues that lysine oxidase naturally occurs in human tissues and has been responsible for crosslinking reactions as demonstrated by Stedronsky and Urry. These arguments, however, do not adequately demonstrate a reasonable expectation of success in substituting lysine oxidase for transglutaminase in Richardson et al. even if, *arguendo*, such a substitution would result in the methods of the rejected claims. In addition, Applicant notes that Urry teaches that "not all lysine-containing peptides are capable of acting as substrates of lysyl oxidase". This teaching is contrary to the Examiner's allegation that one of ordinary skill in the art would expect that substituting the enzymes would necessarily be successful.

Finally, Applicant again notes for the record that the teachings of Stedronsky do not provide crosslinking of the sealant to tissue via lysine oxidase, rather the use of the enzyme was for the purpose of crosslinking the sealant to itself.

Based on the above arguments, Applicant respectfully requests reconsideration of this rejection.

Double Patenting Rejections

The Examiner has rejected claims 1-10, 24, 35, 51, 95-104 and 108 under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-46 and 48 of US. Patent No. 6,267,957 in view of Stedronsky, Urry and Webster's dictionary (p. 857).

Applicant respectfully traverses. For the reasons provided above, Applicant maintains that the Examiner has not demonstrated that one of ordinary skill in the art would have been motivated to substitute transglutaminase with lysine oxidase nor have a reasonable expectation of success in doing so.

Based on the above arguments, Applicant respectfully requests reconsideration of this rejection.

The Examiner has rejected claims 1-10, 24, 35, 51, 95-104 and 106-118 under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 22, 25, 145-152, 155, 156, 158-165 and 167-173 of US. Patent No. 6,958,148 in view of Stedronsky, Urry and Webster's dictionary (p. 857).

Applicant respectfully traverses. For the reasons provided above, Applicant maintains that the Examiner has not demonstrated that one of ordinary skill in the art would have been motivated to substitute transglutaminase with lysine oxidase. Further, as argued above, the Examiner has not demonstrated that there would have been a reasonable expectation of success from the substitution based on the art cited by the Examiner.

Based on the above arguments, Applicant respectfully requests reconsideration of this rejection.

The Examiner has provisionally rejected claims 1-10, 24, 36, 51, 95-104 and 106-118 under the judicially created doctrine of obviousness-type double patenting, as allegedly being unpatentable over claims 1-52 of copending Application No. 11/144372 in view of Stedronsky, Urry and Webster's Dictionary.

The Examiner has raised a provisional double patenting rejection based on a copending, unallowed application. For the same reasons set forth above, Applicant maintains that the claimed invention is not obvious over the cited art, and, therefore, Applicant submits that the double patenting rejection does not apply. In view of the unallowed state of the copending application, however, Applicant maintains the right to further address this rejection in the event the rejection is maintained and does not at this time wish to file a terminal disclaimer.

Accordingly, withdrawal of this rejection is respectfully requested.

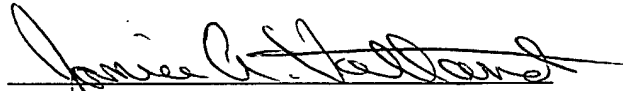
The Examiner provisionally rejected claims 1-10, 24, 36, 51, 95-104 and 106-118 under the judicially created doctrine of obviousness-type double patenting, as allegedly being unpatentable over claims 1-50 of copending Application No. 11/125830 in view of Stedronsky and Urry.

The Examiner has raised a further provisional double patenting rejection based on a copending, unallowed application. Again, for the same reasons set forth above, Applicant maintains that the claimed invention is not obvious over the cited prior art, and, therefore, Applicant submits that the double patenting rejection does not apply. In view of the unallowed state of the copending application, however, Applicant maintains the right to further address this rejection in the event the rejection is maintained and does not at this time wish to file a terminal disclaimer.

Accordingly, withdrawal of this rejection is respectfully requested.

In view of the above amendment, Applicant believes the pending application is in condition for allowance.

Respectfully submitted,



Janice A. Vatland, Ph.D.
Registration No.: 52,318
WOLF, GREENFIELD & SACKS, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
(617) 646-8000

Date: November 20, 2006
x11.18.06